

**SUMMARY OF THE  
ACCREDITING AUTHORITY COMMITTEE MEETING  
November 4, 1999**

The Accrediting Authority Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Thursday, November 4, 1999, at 1:00 p.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. John P. Anderson of the Illinois Environmental Protection Agency, Division of Laboratories. A list of action items is given in Attachment A. A list of participants is given in Attachment B. Attachment C lists 30 suggested changes to Chapter 6 submitted by the EPA Regional assessors who served as lead assessors for the evaluation of the first round of accrediting authorities applying for NELAP recognition.

## **INTRODUCTION**

Mr. John Anderson, Chairman, opened the meeting and requested that members refer to the agenda he had provided them prior to the teleconference. He reported that Ms. Jeanne Mourrain, NELAP Director, would participate in the meeting to discuss the Accrediting Authority Committee's proposal for revising Section 1.6.3 of Chapter 1.

## **SPECIFIC ISSUES**

Section 1.6.3 of Chapter 1 - Building on the framework agreed to at NELAC V in Saratoga Springs, NY, for appointing the Accrediting Authority Review Board (AARB) and assigning it responsibility to monitor and audit NELAP procedures for recognizing accrediting authorities, the Committee discussed and agreed to forward its proposed revision to Section 1.6.3 to the Program Policy and Structure Committee. The Committee's discussion led to a final proposal that addressed the concerns of the Ms. Jeanne Mourrain, NELAP Director. She is, however, going to check with the USEPA legal staff to determine the acceptability of a non-voting, private sector representative on the AARB. The major provisions of the proposal agreed upon by the AA Committee are:

1. The AARB will be composed of five voting members and two non-voting members, as follows:
  - a. Four individuals from state accrediting authorities, three of which must be from NELAP recognized state accrediting authorities;
  - b. One individual from a federal accrediting authority;
  - c. One non-voting individual from the USEPA; and
  - d. One non-voting individual from a NELAP-accredited laboratory.
2. All appointees, except the USEPA appointee, are to be made by the NELAP Director from a list of four nominees submitted to him/her by the Environmental Laboratory Advisory Board and the Accrediting Authority Committee.

3. Voting members of the AARB shall not be NELAP staff, on the NELAC Board of Directors or a member of a NELAC standing committee.

4. The primary duties of the AARB are:

- a. To monitor NELAP to assure that USEPA is following the NELAC standards for recognizing accrediting authorities;
- b. To serve as an appeal board for accrediting authorities having a disagreement with an action taken by the NELAP Director. The final decision, however, remains with the NELAP Director;
- c. To report on its activities to the NELAC Board of Directors at each annual meeting; and
- d. To conduct an annual audit of the NELAP process.

The Committee discussed a list of 30 suggested changes to Chapter 6 prepared by the EPA Regional assessors, who served as lead assessors on the evaluations and on-site audits of the first round of applications from accrediting authorities seeking NELAP recognition. The Committee agreed with six of the suggested changes but did not accept 24 of the suggested changes. A detailed listing of all 30 suggestions and the Committee's responses is appended as Attachment C. A summary of the Committee's response to the suggestions it did not accept is contained in the following three paragraphs.

One suggested change not accepted would have allowed a secondary accrediting authority to request of laboratories seeking secondary accreditation some documentation of laboratory operations that would have been submitted to the laboratory's primary accrediting authority. Since Section 6.2.1 on reciprocity is very explicit about what a secondary accrediting authority can and cannot request, and since that language was hammered out during extensive Committee discussions over a period of more than a year, the Committee was not willing at this time to make any changes to the reciprocity section.

Several of the suggested changes not accepted concerned the time frames for turnaround of documents during the application review process. The Committee did not accept those changes at this time because it was felt that meeting the turnaround times currently set forth in Chapter 6 are important to help ensure that the application review process does not become excessively long. Further, the Committee felt that this first round of applications was not representative of the pace applications would be submitted by accrediting authorities during a more normal period of NELAP operations.

Another category of suggested changes would have resulted in a significant philosophical change in the way application reviews are conducted for accrediting authorities seeking NELAP recognition. These changes would have virtually eliminated the currently-required office review, prior to the on-site audit, of all documentation supplied with the application. Adoption of these suggested changes would have allowed the documents to be reviewed during the on-site audit. The Committee rejected this approach because it believes the on-site audit should be devoted solely to determining whether or not an

applicant accrediting authority is actually operating as set forth in the documentation included as part of the application, provided, of course, that the documentation is acceptable and meets all of the requirements set forth in the NELAC standards. The Committee further believes that scarce resources available for on-site audits should not be diverted to evaluating whether or not the applicant accrediting authority's laboratory accreditation program documentation meets the NELAC standards. Such a diversion of resources and departure from the application review process envisioned by the Committee when originally developing the process currently contained in Chapter 6 would significantly increase the probability of wide variations in effectiveness of accreditation programs among NELAP-recognized accrediting authorities.

The Committee discussed a request from Ms. Jeanne Mourrain, Director of NELAP, to assist in the review/updating of a checklist used by the NELAP assessment teams when reviewing applications for NELAP recognition from accrediting authorities. Ms. Veronica Rath, Mr. George Krisztian and Mr. Robert Wyeth agreed to review/update the checklist. Their report is to be made at the December 14-17, 1999, interim meeting of NELAC.

In its final item of business for the teleconference, the Committee instructed Ms. Veronica Rath to research and recommend a fine restaurant at which the Committee can continue its tradition of good food and good fellowship one evening during each annual and interim NELAC meeting. Her report is to be made informally to Committee members as they arrive at the NELAC Vi meeting site.

There being no further business, the meeting was adjourned at about 2:35 p.m.

**ACTION ITEMS  
ACCREDITING AUTHORITY COMMITTEE MEETING  
APRIL 6, 1999**

| <b>Item No.</b> | <b>Action</b>   | <b>Date to be Completed</b> |
|-----------------|---|-----------------------------|
| 1.              | Mr. Anderson will forward the final language being proposed for Chapter 1, Section 1.6.3 to Dr. Marcia Davis so that proposal can be discussed during the Program Policy and Structure Committee meeting at NELAC Vi. | November 19, 1999           |
| 2.              | Ms. Veronica Rath, Mr. George Krisztian and Mr. Robert Wyeth are to review/update the application checklist for accrediting authorities seeking NELAP recognition.  | December 14, 1999           |

**PARTICIPANTS  
ACCREDITING AUTHORITY COMMITTEE MEETING  
APRIL 6, 1999**

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| Issue | NELAC Chapter 6 Rev. 7 | Comments from USEPA Regional Assessors  | Changes to Chapter 6 | Chapter 6 Committee Proposed Changes or Comments   |
|-------|------------------------|---|----------------------|--|
| 1.    | 6.2.1.a)               | A secondary accrediting authority may request any existing documentation provided to the primary accrediting authority by the laboratory as part of the application process. In this initial period, especially, states may be more comfortable with additional information. However, the lab should not have to provide any additional information, merely copies of that information provided to the primary accrediting authority. | No Change            | Chapter Four outlines the requirements for an initial application for laboratories seeking NELAP accreditation. Chapter Four does not distinguish between an initial application for use by primary AAs versus secondary AAs. It is the committee's understanding that this is the only information to be provided by laboratories as part of the "initial application". This may be an issue for Chapter Four to address. |
| 2.    | 6.2.1.f)3)             | 1st example of a timeframe that may be over optimistic. The Regional Lead Assessors request that all timeframes be considered and that this be an agenda item for NELAC V.  | No Change            | The committee feels this is a reasonable time period for a primary AA to respond to a secondary AA & NELAP Director regarding a problem. The committee does not envision this as being a common occurrence.  |
| 3.    | 6.2.1.g)               | Increase time to 30 days, which may include as an action referring the dispute to the AARB. Time may be insufficient for this type of dispute. Also the NELAP Director may want to take counsel from the AARB on a particular case.   | No Change            | The committee feels this is a reasonable time period for the NELAP director to respond to this issue. The NELAP director already has authority to conduct unannounced on-site assessments of AAs. Further, the AARB should not be made a party to operational decisions of NELAP—it should truly be an appeal board.   |
| 4.    | 6.2.1.d)1)             | Clarification needed. The Lead Assessors recommend that d)1) and d)2) be combined to avoid any confusion.   | No Change            | There is no 6.2.1 (d)(1) or (d)(2) in revision 7 nor the current revision of the chapter.  |
| 5.    | 6.3.1.b)4)             | Editorial: change assurance to insurance.   | Changed              |  |
| 6.    | 6.3.3.a)               | Extend time to 60 days.   | No Change            | All time these timeframes were originally drafted the intent was to complete action on a recognition request within 9 months (worst case scenario).  |

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| 7.    | 6.3.3.a)4)             | <p>"The NELAP Director shall <b>endeavor to</b> appoint. . ."</p> <p>It will be nearly impossible to change the Regional assessor in many cases. Also, depending on availability and travel funds, it may be difficult to change state assessors.</p> | No Change            | The committee's intent on changing the makeup of the assessment team membership every four years (each on-site assessment) was to promote a cross-fertilization of ideas, expertise and styles. The USEPA member may be from any regional office or headquarters.                    |
| 8.    | 6.3.3.d)               | Add the statement: "The NELAP team may provide assistance to the accrediting authority applicant in areas needed to meet the NELAC requirements."   | No Change            | A change to the standard would not be necessary. Providing assistance ,within reason, would always be allowed.   |
| 9.    | 6.3.3.1.e)             | Typo: . . .by which it receives <b>its</b> financial. . .   | Changed              |  |
| 10.   | 6.3.3.1.'x')           | Include the requirement for SOPs cited in section 6.3.1.b)3).   | No Change            | The committee was not clear on this comment. However, sections 6.3.3.1-6.3.3.1.3 already include terms such as "documented procedures" , "standard operating procedures" or "documented in quality manual".  |
| 11.   | 6.3.3.1.k)             | Modify this section to include the QAO reporting to someone other than the day-to-day manager, that is higher up the chain of command.  | No Change            | This would exclude an "one-person" accreditation program from becoming NELAP recognized. There is a parallel issue with laboratories and Chapter 5. The NELAC standards must not contain any requirement that would automatically disqualify a laboratory or AA because of its size. |

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| 12.   | 6.3.3.2.a)<br>& c)           | <p>These two seem to be internally inconsistent. (See a) “. . . notes no deficiencies. . .” and c)1) “identify any specific deficiencies noted during the application technical review.”)</p> <p>The process that the Regional Lead Assessors have found to be most effective is to go through the two deficiency reports, and resolve any remaining problems during or immediately following the onsite assessment.</p> <p>Misunderstandings on both sides can usually be resolved in a face-to-face meeting that otherwise might require multiple written communications.</p> <p>The Regional Lead Assessors are in total agreement that all deficiencies must be corrected before a state is NELAP-recognized. However, a more flexible system would greatly enhance the effectiveness and efficiency of the overall process.</p> | No Change               | <p>Section 6.3.3.2 (a) addresses the procedure when an application contains no deficiencies. Section 6.3.3.2 (c) the procedure when an application has deficiencies.</p> <p>At the time this section was originally drafted, the committee thoroughly discussed the suggestion of “rolling over” corrective actions to application deficiencies as part of the on-site assessment. The committee feels it is important to make sure that the accreditation program is compliant at least on paper before attempting an on-site assessment. It is felt that the focus of the on-site assessment would then be verification that documented procedures which should have been established and approved by the NELAP assessment team are implemented and that the required records/documentation are maintained.</p> |
| 13.   | 6.3.4.a)2)                   | Add day-to-day manager as one of the changes which require notification.   | Changed                 | This was changed in revision 8 to include “including key personnel” which would include the day-to-day manager.   |
| 14.   | 6.4.1.a)                     | Change “accepts” to “completes the technical review”. There is no clear definition of “accepts”. Also, see comment on 6.3.3.2.a).  | Will Change             | An earlier draft of this Chapter used the term “approves”. After deliberation, the consensus of the committee was to change to this to “accepts for continued processing” (See 6.3.3.2 (a)). Section 6.4.1 (a) refers to the action in 6.3.3.2 (a). However, the phrase “accepts application for further processing” will be added to 6.4.1 (a).  |
| 15.   | 6.4.1.c)                     | Change “approval of the application” to “the completion of the technical review”. See comment above.   | Will Change             | The committee believes the term “approval” at this stage denotes completion of corrective actions to deficiencies (if applicable) and is more appropriate. It is not clear why the regional assessors would like this wording change. However, the committee will change to “accept for further processing” in this section to be consistent with 6.3.3.2 (a)(b) and 6.4.1 (a).   |
| 16.   | 6.4.2.a)                     | Remove “approval of NELAP Director”. This decision does not need to be condoned by the NELAP Director, and any inconsistencies could be resolved through the Accrediting Authority Review Board.   | No Change               | The AARB should not be involved in the initial decision regarding recognition. Such involvement would compromise its function as an appeal board. This provision was included to provide the NELAP director with some measure of control of the financial costs of conducting the on-site assessments.  |



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| 17.   | 6.4.3.a)               | Add “. . .by certified mail or another equivalent process. . .”. This is to accommodate the use of Fed Ex or other similar mail delivery.   | Will Change          |  |
| 18.   | 6.4.3.d)               | Add “If the on-site assessment reveals deficiencies <u>or there are any remaining deficiencies from the technical review.</u> . . .”. See comment on 6.3.3.2.a).  | No Change            | See comment with issue #12.  |
| 19.   | 6.4.3.e)               | Add a sentence that indicates that for an initial application, the state’s application will be “on hold” until the deficiencies are corrected. None of us have the time to start from scratch if the time limit is not met. If a state requires an additional amount of time to correct the deficiency, the NELAC system will not suffer during an initial application. | No Change            | See comment with issue #12.  |
| 20.   | 6.4.3.f)1) & f)2) & g) | In general the Regional lead assessors would like to see all 20 day timeframes changed to 30 days.  | No Change            | See comment with issue #6  |
| 21.   | 6.4.3.g)1) & g)2)      | Same comment as 6.4.3.e). Allow an unspecified amount of time for initial application.  | No Change            | See comment with issue #6  |
| 22.   | 6.5.a)                 | The July 2000 issue needs to be readdressed by the states. The Regional Lead Assessors do not believe that any state can be fully compliant with the NELAC standards during the initial stage. This issue should be brought to the attention of the states.   | ---                  | Noted  |
| 23.   | 6.6.d)                 | Change to 30 days.  | No Change            | See comment with issue #6  |
| 24.   | 6.8.                   | Betsy Dutrow has nearly completed the negotiations with the Office of General Counsel regarding the logo. She will supply the exact wording to the committee before the July meeting.   | No Change            | The committee has not yet received any language regarding the logos.   |
| 25.   | 6.8.a)                 | The Regional Lead Assessors are unsure what the intent of this clause is. The states should be the decision makers on this issue.   | No Change            | The intent was to require NELAP-recognized AAs to have arrangements (ISO term) to prohibit accredited laboratories from making inaccurate statements regarding its accreditation or misuse of the NELAP/NELAC logos. |

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| 26.   | 6.9.a)                       | Rather than submitting the information to NELAP HQ, where we have no filing space, we suggest that this information be maintained by NELAP, but not specify the exact location. NELAP is operating only with the cooperation and support of the EPA Regions. It must be recognized that although there is a centrally identifiable group, NELAP as a whole can only function in a de-centralized fashion through the Regions. At the present time, the most logical location would be in the EPA Regional files. | No Change               | Since the makeup of the assessment teams may change, it is important that all records regarding each AA's program be centralized at NELAP (where ever that may be) with the NELAP staff responsible for its organization and security.   |
| 27.   | 6.9.1.e)                     | Add "whenever possible". Due to the limited number of on-site inspections performed by the Regional Lead Assessors they may not meet the requirements. This means that the state assessor must always be an active assessor, excluding program managers from the states. A great deal of talent may be lost because of this exclusion. It has proved quite difficult to find sufficient personnel to staff the teams because of limited state travel funds. Therefore, greater flexibility is needed here.       | No Change               | The issue of the makeup of the NELAP assessment team was thoroughly debated at several NELAC meetings. This language had undergone many changes. The current wording contains very minimal and flexible requirements. The committees feels if any changes are to be made the changes should be more restrictive and stringent. |
| 28.   | 6.9.1.b)                     | Inclusion of state assessors from non-NELAP recognized accrediting authorities would prove beneficial to the overall system. Those not routinely involved in implementing NELAC standards can frequently provide a new perspective. In addition, it is an excellent introduction to a state considering NELAP recognition and should encourage broader participation.  | No Change               | Again, the makeup of the NELAP assessment team was discussed thoroughly. It is felt that the states that have invested the time and resources to become NELAP-recognized would be the most experienced individuals to evaluate implementation of the NELAC standards by an applicant AA.                                       |
| 29.   | 6.9.1.e)2)D<br>)             | Can this requirement be interpreted to include laboratory <u>certification or inspection</u> programs? If not, please make the appropriate change.   | No Change               | Yes.   |
| 30.   | 6.10. a) &<br>g)             | Change times to 30 days.   | No Change               | See comment with issue #6  |